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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,127	06/19/2003	Carlos Schuler	0047.10	5998

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NEKTAR THERAPEUTICS  
150 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER
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EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

**Application No.**

10/601,127

**Applicant(s)**

SCHULER ET AL.

**Examiner**

Darwin P. Erez

**Art Unit**

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 53-68 is/are pending in the application.
- 4a) Of the above claim(s) 61-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/26/06, 10/27/06
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I in the reply filed on 2/15/07 is acknowledged. The traversal is on the ground(s) that the search for the other group would not pose an undue burden on the Examiner. This is not found persuasive because the search for the device of Group II is more comprehensive than the search for the methodology of Group I, especially since the device of Group II could be used in vaporizing non-pharmaceutical formulations.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 61-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/15/07.

### ***Information Disclosure Statement***

3. The information disclosure statements (IDS) submitted on 6/26/06 and 10/27/06 have been received and made of record. Note the acknowledged forms PTO-1449 enclosed herewith.

### ***Drawings***

4. New corrected drawings in compliance with 37 CFR 1.84(l) are required in this application because the drawing contains lines, numbers & letters that are not uniformly thick and well defined (poor line quality). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark

Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 53-55, 57 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,727,546 to Clarke et al.

(claim 53) Clarke discloses a method for aerosolizing a pharmaceutical formulation, the method comprising:

-providing a valve **27** within an airway (the interior space of the device shown in Figs. 2(a) – 2(c)) leading to the lungs to prevent respiratory gases from flowing to the lungs when a user attempts to inhale (Fig. 2(a) shows the closed position), and then permitting respiratory gasses to flow to the lungs (Fig. 2(b)) by opening the valve when a threshold actuating vacuum caused by the attempted inhalation exceeds the pressure of the spring biasing means **26**;

providing a flow regulator **23** within the airway, wherein the flow regulator varies the flow resistance through the airway to control the flow of respiratory gases (as seen between Figs. 2(b)-2(c)); and

using the flow of respiratory gases to extract a pharmaceutical formulation from a receptacle 11 (shown in Fig. 1(a)) and to place said formulation within the flow of respiratory gases to form an aerosol.

(claim 54) Clark discloses the desired negative pressure created in the mouthpiece to be in the range of 0.1-20 mbar, which is equivalent to 0.1-20.29 cm H<sub>2</sub>O (see col. 5, lines 2-4).

(claim 55) The flow regulator 23 is fully capable of limiting the flow of gas to a rate that is less than a higher rate.

(claim 57) The flow regulator 23 regulates the size of the airway.

(claim 59) The valve 27 and the flow regulator 23 are arranged in series.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 3731

9. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. in view of US 6,116,237 to Schultz et al.

Clarke discloses a desired flow rate of between 20-250 l/min. Clarke fails to teach the specific flow rate of 15 l/min. However, Schultz discloses that a flow rate of 15-60 l/min is required to provide a better delivery efficiency of powder medicaments (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methodology of Clarke to include the flow rate of 15 l/min because certain dry powder medicament require a lower flow rate for better delivery efficiency of the medicament into lungs.

10. Claims 58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al.

(claim 58) Clarke teaches the embodiment of the flow regulator **23** shown in Figs. 2(a)-2(c) as a vane. However, Clarke discloses various other embodiment for the flow regulator, including a duck bill valve shown in Fig. 9(a). These are disclosed as equivalent structures known in the art. Therefore, since these embodiments were art-recognized equivalent at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute one embodiment for the other.

(claim 60) Clarke teaches the valve **27** and the flow regulator **23** being arranged in series, as shown in Figs. 2(a)-2(c). Clarke fails to teach a parallel arrangement. However, it would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to modify the arrangement from a series arrangement to a parallel arrangement because Applicant has not disclosed that

Art Unit: 3731

parallel arrangement provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the series arrangement or the claimed parallel arrangement because both arrangements perform the same function of regulating air flow to the patient. Furthermore, the applicant has not provided any criticality to a "parallel" arrangement since the applicant discloses that the invention could either have a series or parallel flow arrangement.

Therefore, it would have been obvious matter of design choice to modify the invention of Clarke to obtain the invention as specified in claim 60.

### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 3731

12. Claims 53 and 54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,606,992. For double patenting to exist between the rejected claims and the patented claims, it must be determined that the rejected claims are not patentably distinct from the patented claims. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and the recited patented claims and, if so, whether those differences render the claims patentably distinct.

Claim 53 recites a method comprising providing a valve, a flow regulator, and using the flow of respiratory gases to extract a pharmaceutical formulation

It is clear that all the elements of claim 53 are to be found in claim 8 of the patent. The difference between claim 53 of the application and claim 8 of the patent lies in the fact that the patent claim includes additional elements and is thus much more specific (e.g. spring biasing ball flow regulator). Thus the invention of claim 8 of the patent is in effect a "species" of the "generic" invention of claim 53 of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 53 of the application is anticipated by claim 8 of the patent, it is not patentably distinct.

Claim 8 of the patent also reads over the limitation of claim 54 of the application.

### ***Conclusion***

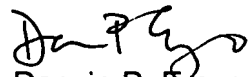
13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Darwin P. Erezzo  
Examiner  
Art Unit 3731

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